REMARKS

Claims 1-11 are pending in this application.

The rejection of claims 1-3, 5-9 and 11 under 35 U.S.C. § 102(a)

The Examiner has rejected claims 1-3, 5-9 and 11 under 35 U.S.C. § 102(a) as anticipated by Geusens et al., J of Clin Densitometry, 2001;4:389-394. According to the Examiner, Geusens discloses the case history of an 18-year old boy treated with intravenous pamidronate (a biphosphanate) for extreme back pain resulting from multiple vertebral fractures. Applicant respectfully traverses this rejection.

Claim 1, the only independent claim, reads:

> A method of treating chronic spinal mechanical pain which comprises intravenously administering to a subject in need of chronic spinal mechanical pain relief an effective amount for relieving spinal mechanical pain of a bisphosphonate. (emphasis added)

The specification defines "chronic spinal mechanical pain" to mean "any back pain lasting more than twelve weeks which is not caused by cancer, or an osteoporotic compression fracture" (specification, page 7, lines 15-16). Geusens does not disclose or suggest treating chronic spinal mechanical pain, as the term is defined in the specification, for the following reasons.

The patient disclosed in Geusens has vertebral fractures resulting from glucocorticoid-induced osteoporosis (see, e.g., Geusens abstract and page 393, left column, 2nd paragraph). These osteoporotic fractures are compression fractures:

(1) The patient lost 2 cm in height between the ages of 16 and 18 (Geusens, page 390, right column, 2nd paragraph). This corresponds to the time the fractures developed (Geusens, abstract). A loss of height is consistent with multiple vertebral compression fractures. *See* Silverman SL, Bone, 1992;13(Suppl. 2):S27-31) (abstract only) (Vertebral compression fractures "may be defined as a clinical event characterized by loss of height ..."); Keller et al., Spine, 2003;28(5):455-62 (abstract only) (A biomechanical model, which "qualitatively resembled deformities observed in ... osteoporotic compression fractures" produced an 8.6% decrease in total body height) (copies enclosed).

(2) Figure 1C shows an X-ray of the fractures in which the anterior heights of the fractured vertebrae are less than the posterior heights of the vertebrae (Geusens, page 391). This is consistent with the radiographic appearance of vertebral compression fractures. As shown in Wu et al., J Clin Neurosci. 2006;13(1):31-38 (abstract only) (copy enclosed), vertebral compression fractures involve the anterior column only or the anterior and middle columns (not the posterior column).

Thus, Geusens discloses the treatment of an osteoporotic compression fracture. Such a fracture does not fall within the definition of chronic spinal mechanical pain. Accordingly, this rejection should be withdrawn.

The rejection of claims 1, 4 and 10 under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1, 4 and 10 under 35 U.S.C. § 103(a) as obvious over Urban et al., Society for Neuroscience Abstracts, 2001;27(1):1326 in view of U.S. Patent No. 6,676,970. According to the Examiner, Urban discloses that zoledronate (a bisphoshonate) produces an anti-allodynic effect in rats, and Bader discloses parental zoledronate preparations. The Examiner contends that it would have been obvious to one of ordinary skill in the art to use intravenous zoledronate to treat pain based on these references. Applicant respectfully traverses this rejection.

Urban discloses treating bone cancer-induced pain in rats using zoledronate. Bader discloses treating osteoporosis using bisphosphonates (see, e.g., Bader at column 3, lines 46-54; column 5, lines 19-21). These references do not disclose or suggest treating chronic spinal mechanical pain, i.e., back pain lasting more than twelve weeks which is not caused by cancer or an osteoporotic compression fracture. Accordingly, the instant claims are nonobvious over the combination of Urban and Bader.

Conclusion

No new matter has been introduced. The pending claims are all believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If any points remain in question, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Dated: Janurary 8, 2007

Respectfully submitted,

By _____

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1: Bone. 1992;13 Suppl 2:S27-31.

Links

The clinical consequences of vertebral compression fracture.

Silverman SL.

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Vertebral compression fractures (VCFs) may be defined radiographically or as a clinical event. The prevalence of these fractures in women aged 50 and over has been estimated at 26% when defined as a reduction in vertebral height greater than 15%. Retrospective reviews of case records have shown a clinical detection rate of VCF in white women of 153/100,000 person years. Of these clinically detected VCFs, 84% were associated with pain. VCF may be defined as a clinical event characterised by loss of height and acute pain. The pain of acute fracture usually lasts 4 to 6 weeks with intense pain at the site of fracture. Chronic pain may also occur in patients with multiple compression fractures, height loss and low bone density but is probably due to structural changes or osteoarthritis. Radiographic VCF may not be symptomatic. The greater the deformity, the greater the likelihood of pain and disability. As height is lost, patients experience discomfort from the rib cage pressing downward on the pelvis. Patients develop a thoracic kyphosis, a lumbar lordosis, and a protuberant abdomen with prominent horizontal skinfold creases. The reduced thoracic space may result in decreased exercise tolerance and reduced abdominal space may give rise to early satiety and weight loss. Sleep disorders may also occur. Patients lose self esteem. Self care may become difficult. They are often depressed. They become fearful of further fracture. They have distorted body image and poor health perception. Patients with one vertebral fracture are at increased risk of peripheral fracture and further vertebral fracture. The aims of acute management are to reduce symptoms and mobilise the patient as quickly as possible.(ABSTRACT TRUNCATED AT 250 WORDS)

PMID: 1627411 [PubMed - indexed for MEDLINE]

Related Links

Acute versus chronic vertebral compression fractures treated with kyphoplasty: early results.[Spine J. 2004]

Restoring geometric and loading alignment of the thoracic spine with a vertebral compression fracture: effects of balloon (bone tamp) inflation and spinal extension. [Spine J. 2005]

Preliminary outcomes and efficacy of the first 360 consecutive kyphoplasties for the treatment of painful osteoporotic vertebral compression fractures. [Spine J. 2005]

Association of osteoporotic vertebral compression fractures with impaired functional status. [Am J Med. 1993]

Kyphoplasty reduction of osteoporotic vertebral compression fractures: correction of local kyphosis versus overall sagittal alignment. [Spine. 2006]

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1: Spine. 2003 Mar 1;28(5):455-62.

Prediction of osteoporotic spinal deformity.

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STUDY DESIGN: A biomechanical model was developed from full-spine lateral radiographs to predict osteoporotic spinal deformity in elderly subjects. OBJECTIVE: To investigate the biomechanics of age-related spinal deformity and concomitant height loss associated with vertebral osteoporosis. SUMMARY OF BACKGROUND DATA: Vertebral bone loss and disc degeneration associated with aging causes bone and disc structures to weaken and deform as a result of gravity and postural stresses. METHODS: An anatomically accurate sagittal-plane, upright-posture biomechanical model of the anterior spinal column (C2-S1) was created by digitizing lateral full-spine radiographs of 20 human subjects with a mean height of 176.8 cm and a mean body weight of 76.6 kg. Body weight loads were applied to the model, after which intervertebral disc and vertebral body forces and deformation were computed and the new spine geometry was calculated. The strength and stiffness of the vertebral bodies were reduced according to an osteopenic aging model and modulus reduction algorithm, respectively. RESULTS: The most osteopenic model (L3 F(ult) = 750 N) produced gross deformities of the spine, including anterior wedge-like fracture deformities at T7 and T8. In this model, increases in thoracic kyphosis and decreases in vertebral body height resulted in a 25.2% decrease in spinal height (C2-S1), an 8.6% decrease in total body height, and a 15.1-cm anterior translation of the C2 spine segment centroid. The resulting deformity qualitatively resembled deformities observed in elderly individuals with osteoporotic compression fractures. CONCLUSIONS: These predictions suggest that postural forces are responsible for initiation of osteoporotic spinal deformity in elderly subjects. Vertebral deformities are exacerbated by anterior translation of the upper spinal column, which increases compressive loads in the thoracolumbar region of the spine.

PMID: 12616157 [PubMed - indexed for MEDLINE]

1: J Clin Neurosci. 2006 Jan;13(1):31-8.

Classification of symptomatic osteoporotic compression fractures of the thoracic and lumbar spine.

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The pathophysiology of osteoporotic compression fractures is different from those occurring secondary to traumatic spinal injury, and currently, there is no classification suitable for symptomatic osteoporotic compression fractures treated by percutaneous vertebroplasty. We propose a new classification based on the radiological appearance in the subacute or chronic stage of the clinical presentation of these fractures. They are classified by the authors based on observations and measurements from preoperative and postoperative dynamic lateral radiographs. Compression fractures are divided into two types. Type I is a compression fracture involving the anterior column only. Type II is a fracture involving both the anterior and middle column. Each type is divided into two groups: fractures with union and those with non-union. Type II compression fractures have a higher incidence of non-union than type I ($p<0.05$). In both type I and II non-union groups, fractures achieve greater increase in vertebral body height after vertebroplasty than both type I and type II union group fractures ($p<0.05$). In both non-union groups, fractures achieved a greater reduction of kyphotic angle post-vertebroplasty than type I and II union group fractures ($p<0.05$). Further clinical follow-up of these patients will confirm and extend this classification.

PMID: 16410195 [PubMed - indexed for MEDLINE]